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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,230	02/16/2006	Gisela Gauchel	KWO-18902/01	5656
25006	7590	05/27/2009	EXAMINER	
GIFFORD, KRASS, SPRINKLE, ANDERSON & CITKOWSKI, P.C			MOSS, KERI A	
PO BOX 7021			ART UNIT	PAPER NUMBER
TROY, MI 48007-7021			1797	
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			05/27/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/535,230	<b>Applicant(s)</b> GAUCHEL, GISELA	
	<b>Examiner</b> KERI A. MOSS	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicant's amendment filed February 5, 2009 is hereby acknowledged. Newly added claims 25-26 are pending. Claims 1-24 have been cancelled.

### ***Response to Amendment***

2. All previously rejected claims have been cancelled. Applicants have added claims 25-26.

Claims 25-26 have been rejected under 35 USC § 112, 2<sup>nd</sup> paragraph.

### ***Claim Rejections - 35 USC § 112***

3. Claims 25-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. In claim 25, the preamble does not clearly and distinctly point out the nature of the invention. The claim is for "an in vitro method of diagnosis" but the invention is one for determining improper manipulation. The examiner recommends clarifying that the invention is a method for determining improper manipulation by the test subject during testing of a urine sample, wherein prior to providing the sample, the test subject is administered marker substances PEG (polyethylene glycols) that are only slightly metabolizable or are non-metabolizable and thus are detectable in urine.
5. Also in claim 25, the use of "in which" in the preamble is confusing. Please replace with "wherein."

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6. Also in claim 25, the use of "diagnosable" is confusing. PEG is not a disease or condition of the subject, thus the word "detectable" seems more appropriate.

7. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how improper manipulation is determined. The invention is for the determination of improper manipulation, yet the claim does not explain how that determination is made. Since the chromatogram is already mentioned in the claim, it would provide clarity to specify that the sample is analyzed. Thus, the examiner recommends adding a step for analyzing the urine sample with chromatography, wherein the detection of the metabolizable substance in the urine sample demonstrates improper manipulation by the test subject.

8. Dependent claim 26 is properly rejected for the same reasons as claim 25.

### ***Allowable Subject Matter***

9. Claims 25-26 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

10. The following is a statement of reasons for the indication of allowable subject matter: The closest prior art, Keller et al., does not teach or suggest administering at the same time and in addition to the polyethylene glycols marker substances, a metabolizable substance comprising at least one of a derivative of benzoic acid or 4-hydroxy-benzoic acid in order to detect manipulation. Keller et al. does not teach or suggest administering a substance that is metabolizable. Keller actually teaches away

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from adding a second marker that is metabolizable because Keller teaches that the detection of polyethylene glycol in the urine sample “unequivocally” assigns the test sample to the subject. Further, while the metabolic behavior of derivatives of benzoic acid or 4-hydroxy-benzoic acid in the human body is known (See Quick, The Conjugation of Benzoic Acid in Man, J. Biol. Chem, vol. 92, pages 65-85 (1931)), the prior art does not teach or suggest a method of using these compounds to detect improper manipulation during testing of a urine sample by administering it to a subject along with a slightly metabolizable or non-metabolizable polyethylene glycol.

### ***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to KERI A. MOSS whose telephone number is (571)272-8267. The examiner can normally be reached on 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Keri A. Moss/  
Examiner, Art Unit 1797

/Vickie Kim/

Supervisory Patent Examiner, Art Unit 1797